Claims

1. A method of reducing or alleviating one or more side effects of anti-retroviral drug therapy comprising administering to a subject a poxvirus vector encoding an antigen of the retrovirus or the retrovirus antigen and a cytokine, or a functional homolog, derivative, part or analog of the retrovirus antigen and/or the cytokine, in conjunction with interrupted anti-retroviral drug therapy wherein the antigen or the antigen and the cytokine are expressed in the subject and are effective in maintaining or prolonging a low retroviral load in the subject for a period of time and are effective in preventing, reducing or delaying viral rebound during interruption of anti-retroviral drug treatment.

2. The method of claim 1, wherein the retroviral infection is HIV infection.

3. The method of claim 1 or 2, wherein the vector is administered to a subject exhibiting a low retroviral viral load as a result of anti-retroviral drug therapy.

4. The method of claim 1 or 2, wherein the vector is administered to a subject exhibiting a low retroviral load prior to commencement of anti-retroviral drug therapy.

5. The method of claim 1, 2, 3 or 4, wherein the cytokine is selected from IFNγ, IL-12, IL-2, TNF and IL-6.

6. The method of claim 5, wherein the cytokine is IFNγ.

7. The method of any one of claims 1 to 6, wherein the retrovirus antigen is encoded by a coding region selected from *gag*, *env*, *pol* and *pro* coding regions.

8. The method of claim 7, wherein the retrovirus antigen is encoded by *gag* and/or *pol* coding regions.

9. The method of claim 8, wherein the retrovirus antigen is encoded by *gag* and *pol* coding regions of HIV.

10. The method of any one of claims 1 to 9, wherein the poxvirus vector is an avipox virus vector.

11. The method of claim 10, wherein the avipox virus vector is a fowlpox virus vector.

12. A method for reducing or alleviating one or more side effects of anti-HIV drug therapy comprising administering to a subject a poxvirus vector comprising a sequence of nucleotides encoding a retrovirus antigen and a sequence of nucleotides encoding a cytokine, or a functional homolog, part, derivative or analog of the antigen and/or the cytokine, in conjunction with interrupted anti-retroviral drug therapy, wherein said method is effective in maintaining a low retroviral load in the subject and preventing, reducing or delaying retroviral rebound in the absence of anti-retroviral drug therapy.

13. The method of claim 12, wherein the retrovirus antigen is an HIV antigen.

14. The method of claim 12 or 13, wherein the vector is administered to a subject exhibiting a low retroviral viral load as a result of anti-retroviral drug therapy.

15. The method of claim 12 or 13, wherein the vector is administered to a subject exhibiting a low retroviral load prior to commencement of anti-retroviral drug therapy.

16. The method of claim 12, 13, 14 or 15, wherein the cytokine is selected from IFNγ, IL-12, IL-2, TNF and IL-6.

17. The method of claim 16, wherein the cytokine is IFNγ.

18. The method of claim 17, wherein IFNγ comprises the amino acid sequence set forth in SEQ ID NO: 6 or an amino acid sequence having at least about 60% similarity thereto.

19. The method of claim 17, wherein IFNγ is encoded by a sequence of nucleotides set forth in SEQ ID NO: 5 or a sequence of nucleotides encoding a functional homolog, part, derivative or analog thereof having at least 60% similarity thereto, or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.

20. The method of any one of claims 12 to 19, wherein the retrovirus antigen is encoded by a coding region selected from *gag, env, pol* and *pro* coding regions.

21. The method of claim 20, wherein the retrovirus antigen is encoded by *gag* and/or *pol* coding regions.

22. The method of claim 21, wherein the retrovirus antigen is encoded by *gag* and *pol* coding regions of HIV.

23. The method of claim 22, wherein the retrovirus antigens encoded by *gag* and *pol* comprise the amino acid sequence set forth in SEQ ID NO: 2 or a functional homolog, part or derivative thereof or a sequence of amino acids having at least 60% similarity thereto, and SEQ ID NO: 4 or a functional homolog, part or derivative thereof, or a sequence of amino acids having at least 60% similarity thereto, respectively.

24. The method of claim 22, wherein the retrovirus antigen encoded by *gag* is encoded by a sequence of nucleotides set forth in SEQ ID NO: 1 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment or a sequence which hybridises

thereto or to a complementary form thereof under conditions of medium stringency, and wherein the retrovirus antigen encoded by *pol* is encoded by a sequence of nucleotides set forth in SEQ ID NO: 3 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.

25. The method of any one of claims 12 to 24, wherein the poxvirus vector is an avipox virus vector.

26. The method of claim 25, wherein the avipox virus vector is a fowlpox virus vector.

27. The method of claim 26, wherein the insertion site in the fowlpox vector comprises the sequence of nucleotides set forth in SEQ ID NO: 7.

28. A method of reducing or alleviating one or more side effects of anti-retroviral drug therapy comprising administering to a subject exhibiting a retroviral infection a poxvirus vector comprising a sequence of nucleotides encoding an antigen of the retrovirus or a functional derivative, homolog, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional derivative, homolog, part or analog thereof in conjunction with interrupted anti-retroviral drug therapy, for a time and under conditions sufficient to co-express the antigen and the cytokine and to reduce or alleviate one or more side effects of anti-retroviral drug therapy in the subject.

29. The method of claim 28, wherein the retroviral infection is HIV infection.

30. The method of claim 28 or 29, wherein the vector is administered to a subject exhibiting a low retroviral viral load as a result of anti-retroviral drug therapy.

31. The method of claim 28 or 29, wherein the vector is administered to a subject

exhibiting a low retroviral load prior to commencement of anti-retroviral drug therapy.

32. The method of claim 28, 29, 30 or 31, wherein the cytokine is selected from IFNγ, IL-12, IL-2, TNF and IL-6.

33. The method of claim 32, wherein the cytokine is IFNγ.

34. The method of claim 33, wherein the IFNγ comprises the amino acid sequence set forth in SEQ ID NO: 6 or an amino acid sequence having at least about 60% similarity thereto.

35. The method of claim 33, wherein IFNγ is encoded by a sequence of nucleotides set forth in SEQ ID NO: 5 or a sequence of nucleotides encoding a functional homolog or derivative thereof having at least 60% similarity thereto, or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.

36. The method of any one of claims 28 to 35, wherein the retrovirus antigen is encoded by a coding region selected from *gag*, *env*, *pol* and *pro* coding regions.

37. The method of claim 36, wherein the retrovirus antigen is encoded by *gag* and/or *pol* coding regions.

38. The method of claim 37, wherein the retrovirus antigen is encoded by *gag* and *pol* coding regions of HIV.

39. The method of claim 38, wherein the retrovirus antigens encoded by *gag* and *pol* comprise the amino acid sequence set forth in SEQ ID NO: 2 or a functional homolog, part or derivative thereof, or a sequence of amino acids having at least 60% similarity thereto, and SEQ ID NO: 4 or a functional homolog, part or

derivative thereof, or a sequence of amino acids having at least 60% similarity thereto, respectively.

40. The method of claim 38, wherein the retrovirus antigen encoded by *gag* is encoded by a sequence of nucleotides set forth in SEQ ID NO: 1 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof, having at least 60% similarity thereto after optimal alignment, or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency, and wherein the retrovirus antigen encoded by *pol* is encoded by a sequence of nucleotides set forth in SEQ ID NO: 3 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment, or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.

41. The method of any one of claims 28 to 40, wherein the poxvirus vector is an avipox virus vector.

42. The method of claim 41, wherein the avipox virus vector is a fowlpox virus vector.

43. The method of claim 42, wherein the insertion site in the fowlpox vector comprises the sequence of nucleotides set forth in SEQ ID NO: 7.

44. A use of a recombinant vector comprising a sequence of nucleotides encoding a retrovirus antigen or a functional derivative, homolog, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional derivative, homolog, part or analog thereof in the manufacture of a medicament for use in conjunction with interrupted anti-retroviral drug treatment in maintaining or prolonging a low retroviral load in a subject for a period of time, and in preventing, reducing or delaying viral rebound during interruption of anti-retroviral drug treatment.

45. A use of a recombinant vector comprising a sequence of nucleotides encoding a

retrovirus antigen or a functional derivative, homolog, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional derivative, homolog, part or analog thereof, in the manufacture of a medicament for use in reducing or alleviating one or more side effects of anti-retroviral drug therapy.

46. A use according to claim 44 or 45, wherein the retrovirus is HIV.

47. A recombinant poxvirus vector comprising a sequence of nucleotides encoding a retrovirus antigen or a functional homolog, derivative, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional homolog, derivative, part or analog thereof, when used in conjunction with interrupted anti-retroviral drug therapy to maintain or prolong a low retroviral load in a subject and to prevent, reduce or delay viral rebound during interruption of anti-retroviral drug treatment in a subject.

48. A recombinant poxvirus vector comprising a sequence of nucleotides encoding a retrovirus antigen or a functional homolog, derivative, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional homolog, derivative, part or analog thereof, when used for reducing or alleviating one or more side effects of anti-retroviral drug therapy.

49. The recombinant poxvirus vector of claim 48, when used for maintaining or prolonging a low retroviral load in the subject during anti-retroviral treatment interruption and for reducing or alleviating one or more side effects of anti-retroviral drug therapy.

50. The recombinant poxvirus vector of claims 47, 48 or 49, wherein the retrovirus is HIV.

51. The recombinant vector of claims 47, 48, 49 or 50, wherein the cytokine is selected from IFNγ, IL-12, IL-2, TNF and IL-6.

52. The recombinant vector of claim 51, wherein the cytokine is IFNγ.

53. The recombinant vector of claim 52, wherein the IFNγ comprises the amino acid sequence set forth in SEQ ID NO: 6 or an amino acid sequence having at least about 60% similarity thereto.

54. The recombinant vector of claim 52, wherein IFNγ is encoded by a sequence of nucleotides set forth in SEQ ID NO: 5 or a sequence of nucleotides encoding a functional homolog or derivative thereof having at least 60% similarity thereto or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.

55. The recombinant vector of any one of claims 47 to 54, wherein the retrovirus antigen is encoded by a coding region selected from *gag*, *env*, *pol* and *pro* coding regions.

56. The recombinant vector of claim 55, wherein the retrovirus antigen is encoded by *gag* and/or *pol* coding regions.

57. The recombinant vector of claim 56, wherein the retrovirus antigen is encoded by *gag* and *pol* coding regions of HIV.

58. The recombinant vector of claim 57, wherein the retrovirus antigens encoded by *gag* and *pol* comprise the amino acid sequence set forth in SEQ ID NO: 2 or a functional homolog, part or derivative thereof or a sequence of amino acids having at least 60% similarity thereto, and SEQ ID NO: 4 or a functional homolog, part or derivative thereof or a sequence of amino acids having at least 60% similarity thereto, respectively.

59. The recombinant vector of claim 57, wherein the retrovirus antigen encoded by *gag*

is encoded by a sequence of nucleotides set forth in SEQ ID NO: 1 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency, and wherein the retrovirus antigen encoded by *pol* is encoded by a sequence of nucleotides set forth in SEQ ID NO: 3 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.

60. The recombinant vector of any one of claims 47 to 59, wherein the poxvirus vector is an avipox virus vector.

61. The recombinant vector of claim 60, wherein the avipox virus vector is a fowlpox virus vector.

62. The recombinant vector of claim 61, wherein the insertion site in the fowlpox vector comprises the sequence of nucleotides set forth in SEQ ID NO: 7.